

Notice of Allowability	Application No.	Applicant(s) cc	
	10/052,197	PARODI, JUAN CARLOS	
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment April 15, 2004.
2. ☒ The allowed claim(s) is/are 1-13 and 25-43.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☒ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Rex Donnelly on June 24, 2004.

The application has been amended as follows:

Amendments to the Claims: This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims

1. (Currently Amended) An introducer for insertion in a lumen from a proximal location outside the lumen to a distal location within the lumen for deployment of a prosthesis at a junction of a main lumen and at least one branch lumen, the introducer comprising:

an outer sheath having a distal end;

an axial guide wire slidable within the outer sheath;

at least one peripheral guide wire slidable within the outer sheath, the peripheral guide wire comprising an expandable balloon at a distal end thereof; and

a nose cone located at the distal end of the outer sheath, the nose cone having a periphery, an axial conduit slidable over the axial guide wire, and at least one peripheral channel spaced apart from the axial conduit for receiving one of the peripheral guide wires.

2. (Original) The introducer of claim 1, wherein each peripheral channel is open to the periphery of the nose cone.

3. (Original) The introducer of claim 2, wherein each peripheral channel provides communication between an interior of the introducer and the lumen when the nose cone is positioned at the distal end of the sheath.

4. (Cancelled)

5. (Original) The introducer of claim 1, wherein the at least one peripheral guide wire comprises two peripheral guide wires and the at least one peripheral channel comprises two peripheral channels, each for receiving one of the peripheral guide wires.

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6. (Original) The introducer of claim 5, wherein the two peripheral channels are located at diametrically opposed locations on the nose cone.

7. (Original) The introducer of claim 1 further comprising:

a trunk deployment catheter concentric with the axial guide wire and having at least one inflatable deployment balloon at a distal end thereof; and

at least one peripheral deployment catheter, each concentric with one of the peripheral guide wires and having at least one inflatable deployment balloon at a distal end thereof.

8. (Original) The introducer of claim 7 further comprising:

a prosthesis for deployment in the body lumen, the prosthesis comprising a trunk and at least one arm extending radially from the trunk, the prosthesis adapted to be introduced into the lumen in a compressed configuration with the trunk concentric with the trunk deployment catheter and each arm concentric with one of the peripheral deployment catheters, the prosthesis adapted to be deployed in the lumen in an expanded configuration with the trunk in the main lumen and each arm in one of the branch lumen.

9. (Original) The introducer of claim 8, wherein the prosthesis comprises a graft and at least one stent.

10. (Previously Presented) The introducer of claim 9, wherein the at least one stent comprises:

a distal trunk stent portion expandable for deployment in a distal portion of the main lumen distal the branch lumen;

a proximal trunk stent portion expandable for deployment in a proximal portion of the main lumen proximal the branch lumen; and

at least one branch stent portion expandable for deployment in one of the branch lumens.

11. (Original) The introducer of claim 10, wherein the trunk deployment catheter comprises at least one inflatable deployment balloon for deploying the distal trunk stent portion and at least one inflatable deployment balloon for deploying the proximal trunk stent portion.

12. (Original) The introducer of claim 10, wherein the trunk deployment catheter consists of only a single inflatable deployment balloon maneuverable for deploying both the distal trunk stent portion and the proximal trunk stent portion.

13. (Original) The introducer of claim 10, wherein the distal trunk stent portion, the proximal trunk stent portion and each branch stent portion comprise separate stents.

14.-24. (Cancelled)

25. (Previously Presented) A method for implanting a prosthesis in a distal location within a lumen from a proximal location outside the lumen, the distal location positioned at a junction of a main lumen and at least one branch lumen, the prosthesis comprising at least one stent and having a trunk and at least one arm, each arm for implantation into the branch lumen and the trunk for implantation into the main lumen, the method comprising the steps of:

(a) providing an introducer comprising an outer sheath; an axial guide wire and at least one peripheral guide wire slidable within the outer sheath; a nose cone at a distal end of the outer sheath, the nose cone having an axial conduit slidable over the axial guide wire and at least one peripheral guide channel each for receiving one of the peripheral guide wires, each peripheral guide wire comprising an inflatable anchor balloon at a distal end thereof; a trunk deployment catheter

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- concentric with the axial guidewire and having at least one inflatable deployment balloon; and at least one arm deployment catheter concentric with the peripheral guide wire and having at least one inflatable deployment balloon;
- (b) providing the prosthesis inside the outer sheath with the trunk mounted over the axial guide wire and at least one trunk stent portion mounted over each inflatable deployment balloon of the trunk deployment catheter and each arm mounted over one of the peripheral guide wires and at least one arm stent portion mounted over each inflatable deployment balloon of each arm deployment catheter;
 - (c) introducing the introducer into the lumen until reaching an implantation position adjacent the branch lumen;
 - (d) maintaining the introducer in the implantation position while advancing each peripheral guide wire distally through one of the peripheral channels of the nose cone until each wire is positioned at a sufficient depth within the corresponding branch lumen;
 - (e) inflating each anchor balloon on each peripheral guide wire to fix the wire in a set position;
 - (f) advancing the prosthesis over the axial and peripheral guide wires until each arm of the prosthesis is positioned at a sufficient depth within the branch lumen, and
 - (g) inflating the deployment balloons to expand at least the trunk and arm stent portions of the prosthesis to implant the prosthesis.

26. (Original) The method of claim 25, wherein the main lumen comprises an aorta and the at least one branch lumen comprises the renal arteries, the prosthesis comprises two arms, the introducer comprises two peripheral guide wires and two arm deployment catheters, and the nose cone comprises two peripheral channels, the method further comprising implanting the prosthesis at the junction of the aorta and renal arteries.

27. (Original) The method of claim 26 comprising repairing an aneurysm by implanting the prosthesis.

28. (Original) The method of claim 25, wherein the prosthesis comprises a distal trunk stent portion distal the branch lumen and a proximal trunk stent portion proximal the branch lumen and implanting the prosthesis in step (g) comprises first inflating deployment balloons to deploy the distal trunk stent portion and all arm stent portions, then deflating each arm deployment balloon and retracting each arm deployment catheter at least to a position proximal the proximal trunk stent portion, then inflating a deployment balloon to deploy the proximal trunk stent portion.

29. (Original) The method of claim 28, wherein the trunk deployment catheter comprises a distal deployment balloon and a proximal deployment balloon, the method comprising inflating the distal deployment balloon prior to retracting the arm deployment catheters and inflating the proximal deployment balloon after retracting the arm deployment catheters.

30. (Previously Presented) The method of claim 28, wherein the trunk deployment catheter comprises a single trunk deployment balloon for expanding both the distal trunk stent portion and the proximal trunk stent portion, the method comprising inflating the single deployment balloon to expand the distal trunk stent portion, retracting the arm deployment catheters after expanding the arm stent portions, deflating and partially retracting the trunk

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deployment balloon to a position proximal the proximal trunk stent portion, and re-inflating the trunk deployment balloon to expand the proximal trunk stent portion.

31. (Original) The method of claim 28 wherein step (f) further comprises advancing the nose cone distal of the junction between the branch lumen and the main lumen.

32. (Previously Presented) A method for implanting a modular prosthesis in a distal location within a lumen from a proximal location outside the lumen, the distal location positioned at a junction of a main lumen and at least one branch lumen, the modular prosthesis comprising a trunk module for implantation into the main lumen and comprising at least one stent and at least one arm fitting, the modular prosthesis further comprising at least one arm module for implantation into the branch lumen, the arm module adapted to interconnect with the arm fitting of the trunk module and comprising at least one stent, the method comprising the steps of:

- (a) positioning a first introducer in the main lumen in a first implantation position adjacent the branch lumen, the first introducer comprising an outer sheath; an axial guide wire slidable within the outer sheath; a nose cone at a distal end of the outer sheath, the nose cone having an axial conduit slidable over the axial guide wire; a trunk deployment catheter concentric with the axial guidewire and having at least one inflatable deployment balloon; the modular prosthesis inside the outer sheath with the trunk module mounted over the axial guide wire and at least one trunk stent portion mounted over each inflatable deployment balloon of the trunk deployment catheter
- (b) advancing the nose cone distally to a location distal of the junction of the main lumen with the branch lumen;
- (c) implanting the trunk module with each arm fitting aligned with a corresponding branch lumen by inflating the trunk section deployment balloons to expand the trunk stent portions;
- (d) positioning a second introducer in the main lumen in a second implantation position, the second introducer comprising an outer sheath; an axial guide wire and at least one peripheral guide wire slidable within the outer sheath; a nose cone at a distal end of the outer sheath, the nose cone having an axial conduit slidable over the axial guide wire and at least one peripheral guide channel each for receiving one of the peripheral guide wires, each peripheral wire comprising an inflatable anchor balloon at a distal end thereof; a trunk deployment catheter concentric with the axial guidewire and having at least one inflatable deployment balloon; at least one arm deployment catheter concentric with the peripheral guide wire and having at least one inflatable deployment balloon; each arm module mounted over one of the peripheral guide wires and at least one arm stent portion of each arm module mounted over each inflatable deployment balloon of each arm deployment catheter;
- (e) maintaining the second introducer in the implantation position while advancing each peripheral guide wire distally through one of the peripheral channels of the nose cone and through one of the arm fittings in the implanted trunk module until each peripheral guide wire is positioned at a sufficient depth within the corresponding branch lumen;
- (f) inflating each anchor balloon on each peripheral guide wire to fix the wire in a set position;

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- (g) advancing each arm module over one of the peripheral guide wires until each arm module is positioned at a sufficient depth within the branch lumen and in an interlocking position with one of the arm fittings of the trunk module;
- (h) inflating each arm deployment balloon to expand at least the arm stent portions of each arm module to implant the arm module within the branch lumen and within the corresponding arm fitting of the trunk module.

33. (Original) The method of claim 32 wherein the first introducer and the second introducer are the same introducer, and step (c) is performed with each arm module and arm deployment catheter positioned within the outer sheath proximal of the proximal end of the trunk module, and step (d) comprises retracting the nose cone to a position aligned with the branch lumen.

34. (Previously Presented) A method for implanting a prosthesis in a distal location within the lumen from a proximal location outside the lumen, the distal location positioned at a junction of a main lumen and at least one branch lumen, the prosthesis having a compressed configuration and an expanded configuration and comprising at least one portion for implantation into the branch lumen, the method comprising the steps of:

- (a) providing an introducer comprising an outer sheath; an axial guide wire and at least one peripheral guide wire slidable within the outer sheath; a nose cone at a distal end of the outer sheath, the nose cone having an axial conduit slidable over the axial guide wire and at least one peripheral guide channel for receiving the peripheral guide wire, the peripheral wire comprising an inflatable anchor balloon at a distal end thereof;
- (b) introducing the introducer into the lumen until reaching an implantation position adjacent the branch lumen;
- (c) maintaining the introducer in the implantation position while advancing the peripheral guide wire distally through the peripheral channel of the nose cone until the peripheral guide wire is positioned at a sufficient depth the branch lumen;
- (d) inflating the anchor balloon to fix the peripheral guide wire in a set position;
- (e) advancing the prosthesis over the peripheral guide wire until at least a portion of the prosthesis is positioned at a sufficient depth within the branch lumen, and
- (f) expanding at least a portion of the prosthesis to implant the portion of the prosthesis in the branch lumen.

35. (Original) The method of claim 34 wherein the prosthesis is expanded in step (f) by balloon-expansion.

36. (Newly Added) A prosthesis deployment system for deployment of a prosthesis in a lumen from a proximal location outside the lumen to a distal location within the lumen at a junction of a main lumen and at least one branch lumen, the system comprising:

- an outer sheath having a distal end;
- an axial guide wire slidable within the outer sheath;
- at least one peripheral guide wire slidable within the outer sheath, the peripheral guide wire comprising an expandable balloon at a distal end thereof;

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a nose cone located at the distal end of the outer sheath, the nose cone having a periphery, an axial conduit slidable over the axial guide wire, and at least one peripheral channel spaced apart from the axial conduit for receiving one of the peripheral guide wires; and

a unitary prosthesis comprising a trunk section and at least one arm section extending radially from the trunk section.

37. (Newly added) The system of claim 36, wherein the prosthesis arm section is approximately perpendicular to the prosthesis trunk section.

38. (Newly added) The system of claim 36, wherein the prosthesis comprises two arm sections.

39. (Newly added) The system of claim 36, wherein the prosthesis is adapted to be deployed at a junction in which the main lumen comprises an aorta and each branch lumen comprises a renal artery.

40. (Newly added) The system of claim 36, wherein the prosthesis comprises a graft and at least one stent.

41. (Newly added) The system of claim 40, wherein the at least one stent comprises:
a distal trunk stent portion expandable for deployment in a distal portion of the main lumen distal the branch lumen;

a proximal trunk stent portion expandable for deployment in a proximal portion of the main lumen proximal the branch lumen; and

at least one branch stent portion expandable for deployment in one of the branch lumen.

42. (Newly added) The system of claim 41, wherein the distal trunk stent portion, the proximal trunk stent portion and each branch stent portion comprise separate stents.

43. (Newly added) An introducer for insertion in a lumen from a proximal location outside the lumen to a distal location within the lumen for deployment of a prosthesis at a junction of a main lumen and at least one branch lumen, the introducer comprising:

an outer sheath having a distal end;

an axial guide wire slidable within the outer sheath;

at least one peripheral guide wire slidable within the outer sheath;

a nose cone located at the distal end of the outer sheath, the nose cone having a periphery, an axial conduit slidable over the axial guide wire, and at least one peripheral channel spaced apart from the axial conduit for receiving one of the peripheral guide wires;

a trunk deployment catheter concentric with the axial guide wire and having at least one inflatable deployment balloon at a distal end thereof; and

at least one peripheral deployment catheter, each concentric with one of the peripheral guide wires and having at least one inflatable deployment balloon at a distal end thereof.

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The following is an examiner's statement of reasons for allowance:

None of the prior art of record, alone or in combination, discloses an introducer including a nose cone having an axial conduit and a peripheral channel in combination with a guide wire having an expandable balloon at its distal end, as set forth by the applicant.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaver or McDermott can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
June 24, 2004


DAVID O. REIP
PRIMARY EXAMINER